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EXAMINER	
GEMENIANO, MALOU C	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/501,815	KRETZSCHMAR ET AL.	
	Examiner	Art Unit	
	Malou C. Gemeniano	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~5/11/05~~. 2/13/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In response to Applicant's response filed on 2/13/06, Examiner acknowledges that Group 1, which Applicant elected, pertains to a gene coding for the gamma subunit of AMP-activated protein kinase (AMPKg). Applicant elects Group 1 (claims 1-11) and further elects claims pertaining to phenotypes related to neurodegenerative phenotypes, claims pertaining to a gene encoding for amyloid precursor protein and claims pertaining to transposons. Claims readable on the non-elected species, eg. Claims 9 and 10 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species. The following is an examination of claims 1-8 and 11.

Specification -objections

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 101

Claim Rejections - 35 USC § 101-*Non-Statutory Subject Matter*

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1-3 and 6-8 encompass any organism that expresses a modified version of the gene coding for gamma subunit of AMP-activated protein kinase (AMPKg), the scope of which encompasses any non-human animal that naturally carries mutations of AMPKg, which is a non-statutory subject that emcompasses organisms that are not modified or manipulated by humans. As such, the recitation of the limitation "transgenic" or "genetically modified" would be remedial. See 1077 O.G. 24, April 21, 1987.

Claims 1-3 and 6-8 are drawn to non-human animal that expresses a modified version of the gene coding for the AMPKg and/or a gene encoding amyloid precursor protein. When the claims are given its broadest reasonable interpretation, all non-human animals that carry naturally mutations in AMPKg and express the amyloid precursor protein. This part of the rejection will be overcome by adding "transgenic"or "genetically modified" in claims 1-3 and 6-8.

Claim Rejections - 35 USC § 112-written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention commensurate of the claims encompasses:

(i) a non-human animal;

(ii) a invertebrate;

(iii) a fly

(iv) a modified version of the gene AMPKg;

(v) an identifiable phenotype relating to neurodegenerative phenotype;

(vi) a amyloid precursor protein;

These agents of these claims are broad in scope, being defined on the basis of their effect, and not on any specific structure.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, one or a few phenotypes are given for each of the genera discussed, but do not provide enough phenotypes to allow one to distinguish the differences between the various members of each genera. For example, to claims regarding any modified version of the gene AMPKg wherein the specification teaches a modification wherein Loerig is inserted. However, a modified version of AMPKg encompasses a large genus of modifications such as missenses, truncations, point mutations, silent mutations, frameshift mutations etc. Yet another example, to

claims regarding expression of any amyloid precursor protein which encompasses a large genus of APPL versions; there are mammalian APPL, nematodes APPL, drosopholia APPL, one that is endogenous to the organism, and one that is exogenous to the organism etc. The specification does not provide any disclosure as to what would have been the required structure that would allow one to distinguish the various species of the genera. Next then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e., other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only other characteristics are that they are members of the claimed genera. Such functional characteristics, however, do not allow one of skill in the art to distinguish the different members of the genera from each other.

Applicant's attention is directed to *In re Shokal*, 113 USPQ 283 (CCPA 1957), wherein it is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 CCPA (Patents) 1309, 97 F2d 623, 38 USPQ 189; *In re Wahlforss*, 28 CCPA (Patents) 867, 117 F2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of any non-human animal

or any non-human animal that is an invertebrate that expresses any modified version of the gamma subunit of AMPKg wherein the expression of the said gene results in any identifiable phenotype that is related to any neurodegenerative phenotype at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Claim Rejections - 35 USC § 112-enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

A Drosopholia mutant wherein Leorig (loe) disrupts a specific isoform of the AMPK gamma subunit, wherein loe decreases the amount of secreted of B-amyloid protein precursor-like (APPL) gene wherein the genetically modified drosopholia mutant is characterized with the following phenotypes: Accumulation of fatty acids, dying neurons in the optic system, Vacuolization of the central nervous system, and 40% reduction of cholesterol ester,

does not reasonably provide enablement for any non-human animal and any invertebrate or any genus of fly that expresses any modified version of AMPKg and expresses APPL wherein the expression of the gene result in any identifiable phenotype that is related to any or all neurodegenerative phenotype. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claim

Claims 1-8 and 11 encompass non-human animal that expresses any modified version of AMPKg and expresses APPL wherein the expression of the gene result in any identifiable phenotype that is related to any or all neurodegenerative phenotypes.

Claims 2-3 limit the non-human animal to invertebrate preferably any genus of fly.

The aspects considered broad are: the breadth of a large genus of non-human animal, large genus of invertebrate and large genus of order fly (Order:Diptera) that expresses any modification either genetically modified or natural mutation of AMPKg and expression of any genus of APPL wherein the animal is characterized by large genus of phenotypes that relate to neurodegenerative phenotypes. As will be shown below, these broad aspects are not enabled for their full scope embraced. The detail of the disclosure provided by the Applicant, in view of the prior Art, must encompass a wide area of knowledge to enable one of ordinary skill in the art at the time of the invention to practice the invention without undue experimentation. However, as it will be discussed below this undue experimentation has not been overcome by the as-filed application. And, due to such lack of enablement, some claims are not enabled whatsoever.

State of the prior art

Claims 1-8 and 11 encompasses non-human animal that expresses any modified version of AMPKg and expresses APPL wherein the expression of the gene result in any identifiable phenotype that is related to any or all neurodegenerative phenotypes.

Although the state of the prior art regarding the reliability of generating mutant for the fly homology of the disease associated gene has made Drosopholia a good model system to study neurodegenerative diseases (Chan et al Cell Death and differentiation (2000) &; p. 1705-1080). However, since the claims encompasses a large genus of non-human models, preferably invertebrates and fly, the state of the prior art regarding the genetic manipulation of any non-human animal and/or large genus of invertebrate and/or fly to produce a specific phenotypes is considered unpredictable.

Regarding the claimed invention drawn to genetic modification of any non-human animal, the prior art deemed phenotypes due to genetics modifications of any non-human animals as unpredictable. For example, for non-human animal system such as the mouse expressing a specific phenotype characteristic of all the knockout mice carrying a disruption in the same gene, the art teaches that the resulting phenotype of a knock-out mouse is unpredictable. Holschneider et al., (Int J. Devl. Neuroscience 18:615-618, 2000) states: "knocking out or insertion of a single gene may result in no phenotypic change. This may be the case, in particular, if there exits gene redundancy mechanisms whose presence may prevent abnormal phenotypes from becoming masked. Conversely, single genes are often essential in a number of different behaviors and physiologic processes. Hence, ablation of an individual gene may prove so drastic as to be lethal, or so widespread as to create an amalgam of phenotypes whose interpretation becomes confounded by the interaction of the various new physiologic changes or behaviors" (see, p. 615, columns 1-2). Holschneider et al., discuss various factors that contribute to the resulting phenotype of transgenic mice, including compensatory systems, which may be

de to the differential expression of another gene, which may be regulated by the downstream product of the ablated gene, as well as the variability in phenotypic characterization due to particular mouse strains (see, p. 616, column 1). Further, Leonard (Immunological Reviews, 148:97-114, 1995) discloses mice with a disruption in the Y_c gene that was intended to be a model for X-linked severe combined immunodeficiency (XSCID), but display a variety of unexpected traits (Abstract). These knockout mice were expected to have thymocytes with decreased proliferation in response to stimulation with antibodies, but the thymocytes proliferated normally (page 105, line 7). Griffiths (Microscopy Research and Technique, 41:344-358, 1998) taught that, despite a known role for the PLP gene based on spontaneous mutations in the gene, the knockout mouse failed to display any of the expected phenotypes (page 350, last paragraph). Thus, at the time of filing, the resulting phenotype of a knockout of any non-human animal was considered unpredictable.

Regarding the unpredictability establishing a phenotype using any genetically modified invertebrate and/or fly. Although, drosopholia is known to one ordinary skilled in the art as a supreme and tractable genetic tool (Kretzschmar . Invert. Nerusci. 20005 5:97-109), the claims encompass any invertebrate and/or fly with the claimed genetic manipulations and phenotypes. One ordinary skilled in the art acknowledges that invertebrates would encompass a large genus of organisms such sponges, jellyfish, anemones, corals, worms, mollusks, echinoderms and arthropods. However, the prior art would not deemed the claimed phenotypes of neurodegenerative phenotype as predictable with the genetic maniputlation of these organisms. Likewise, one ordinary skilled in the art acknowledges that the order of "fly" would encompasses the order Diptera which

would encompass a large species of organisms such as gnats, maggots, midges, mosquitos and keds. However, the prior art would not deemed the claimed phenotypes of neurodegenerative phenotype as predictable with the genetic mauniputlation of these organisms. Thus, at the time of filing, the resulting phenotype of a knockout of any invertebrate or any fly was considered unpredictable.

The predictability or lack thereof in the art

The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art.

Guidance in the Specification and working example

Analysis of Quantity of Experimentation

The applicant claims broadly any non-human animal that expresses any modified version of AMPKg and expresses APPL wherein the expression of the gene result in any identifiable phenotype that is related to any or all neurodegenerative phenotype.

First, in regards to the non-human animal, any invertebrate and fly the specification does not describe in sufficient detail and/or provide detail as to obtain any organism other than specifically the fruit fly Drosophila melangaster (p. 4 line 10-15). In view of the unpredictability of the prior art, one ordinary skilled in the art would perform undue experimentation to make a large genus of animals with the neurodegenerative phenotypes commensurate of the claims. As such, there is need for specific detail of methods to make and use the genetically modified animals with the neurodegenerative phenotypes commensurate of the claims. The specifications teach only a Drosopholia

mutant wherein Leorig (loe) disrupts a specific isoform of the AMPK gamma subunit, wherein loe decreases the amount of secreted of B-amyloid protein precursor-like (APPL) (see Example 1). Moreover, if one ordinary skilled in the art was to obtain a non-human animal of the claimed invention, one ordinary skilled would not know if they were in possession of the invention as the Applicant provided no description in the specification of the core structure or characteristic of the non-human animal and one ordinary skilled in the art would not know how to use such an animal in regards to its application towards neurodegenerative diseases. Therefore, one ordinary skilled in the art would have the burden to perform undue experimentation to make and use the invention.

In regards to any identificable phenotype specifically neurodegenerative phenotype, there are no working examples or guidance in the specification in terms of the descriptions of any neurodegenerative phenotypes except for the following: accumulation of fatty acids, dying neurons in the optic system, vacuolization of the central nervous system, and 40% reduction of cholesterol ester. Neurodegenerative disease encompasses a large genus of diseases such as Parkinson, Alzheimer, polyglutamine disorders, Adrenoleuodystrophy, spinomuscular atropy etc. (Penne et al The Journal of clinical investigation Vol, 113 No. 11 p. 2968-2971 : see Figure 1) and within each neurodegenerative disease, there is a large genus of symptoms and phenotypes. However, the specification teaches only the phenotypes of the claimed invention to be accumulation of fatty acids, dying neurons in the optic system, vacuolization of the central nervous system, and 40% reduction of cholesterol ester. The specification lacks sufficient detail, working examples and guidance such as to provide to one skilled in the art to make and use the invention commensurate in scope with all the phenotypes encompassed by neurodegenerative phenotypes.

In view of the unpredictability of the Art, it is essential to provide sufficient description and/or guidance in the specification to provide one ordinary skilled in the art to make and use invention commensurate in scope with all the phenotypes encompassed by neurodegenerative phenotypes. However, Applicant provides no detail of this. Therefore one skilled in the art would have to perform undue experiment to make and use the claimed invention. Therefore, Applicant provides insufficient guidance and/or

working example for a skilled artisan to reasonably enable the claimed invention of any non-human animal that expresses any modified version of AMPKg and expresses APPL wherein the expression of the gene result in any identifiable phenotype that is related to any or all neurodegenerative phenotype.

In order to practice the claimed invention particularly in light of the prior art and guidance or lack thereof, one skilled in the Art would not find it reasonably enabled to make and use any non-human animal that expresses any modified version of AMPKg and expresses APPL wherein the expression of the gene result in any identifiable phenotype that is related to any or all neurodegenerative phenotype. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives transgenic animal with all of the infinite number of derivatives of neurodegenerative phenotypes as recited in claims 1-8 and 11, one skilled in the Art will have to perform extensive experimentation with each of these parameters to find the embodiments embraced by the claims, and as such, this experimentation would be considered undue.

Because of the Extreme Breadth of the Claims, the Following Rejections are Held, Even in Light of the Scope of Enablement

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Milan et al (Science 2000 Vol 288 p. 1248-1251).

With regard to Claims 1, 4, 8 and 11 Milan teach a transgenic pig with a mutation in the PRKAG3 gene which encodes a muscle-specific isoform of the regulatory gamma subunit of adenosine monophosphate-activated protein kinase (**AMPKg**) (see abstract). With regard to Claim 6, Milan teach a pig with an identifiable phenotype specifically defects in glucose metabolism and impaired glycogen synthesis (See Abstract). With regards to claims 8 and 11, Milan anticipates these claims because APPL is a ubiquitous gene expressed in many animals such as mammals, nematodes and drosophila and therefore it is inherent that such animals expresses APPL (Torroja et al. The Journal of Nueroscience 19 (18):7793-7803: see p. 7703 1st ¶).

Claim Rejections - 35 USC § 101 and Claim Rejections - 35 USC § 112

Claims 12-14 and 17 provides for the use of an animal, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-14 and 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites "wherein the said modified version of the gene coding for the gamma subunit of AMP-activated protein kinase (AMPKg) is the loehrig (loe) mutation. It is unclear the subject matter and meaning of this statement. As stands, the interpretation is that a modified version of the gamma subunit of AMK is loerig. In addition, how is that a mutation is AMPKg is loe? Applicant is advised to clearly state the subject matter of claim 5.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The clarity is questioned with the recitations of "modified version of AMPKg and/or APPL". It is unclear if the non-human animal will express the modified version of AMPKg only or express APPL only or the modified version of AMPKg and APPL. As such, there is more than one interpretation of this claim and Applicant is advised to clearly state the subject matter of claim 11.

Claims 5 and 15 recites the limitation "the Loechrig mutation" and "the effect". There is insufficient antecedent basis for this limitation in the claim. These claims recite subject matter that had no antecendent found in claims prior to their recitations in claims 5 and 15.

In conclusion, all claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malou C. Gemeniano whose telephone number is 571-272-6451. The examiner can normally be reached on 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is (571)-272-0532.

For all other customer support, please call the USPTO Call Center (UCC) at (800)-786-9199.

Malou C. Gemeniano, Ph.D
Examiner, USPTO, AU 1632

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